

SEP - 2 1999



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In Re: Patent Term Extension
Application for
U.S. Patent No. Re. 36,128 (4,912,155)

NOTICE OF FINAL DETERMINATION and REQUIREMENT FOR ELECTION

A determination has been made that U.S. Patent No. Re. 36,128,¹ which claims the food additive AQUEOUS ARYL FLUOROPHOSPHITE SUSPENSION® (2,2'-ethylidenebis (4,6-di-tertbutylphenyl)fluorophosphonite), is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be 1,390 days.

A single request for reconsideration of this final determination as to the length of extension of the term of the patent and/or a response to this requirement for an election may be made if filed within may be made if filed within one month of the date of this notice. Extensions of time under 37 CFR § 1.136(a) are not applicable to this time period. In the absence of such request for reconsideration and election, the Commissioner will issue a certificate of extension, under seal, for U.S. Patent No. 4,867,907 and the application for the above-identified patent will be dismissed.

The period of extension has been calculated using the FDA determination of the length of the regulatory review period published in the Federal Register of August 7, 1998 (63 Fed. Reg. 42405). Under 35 U.S.C. § 156(c):

$$\begin{aligned}\text{Period of Extension} &= \frac{1}{2} (\text{Testing Phase}) + \text{Approval Phase} \\ &= \frac{1}{2} (935 - 442) + 1,995 \\ &= 2,242 \text{ days}\end{aligned}$$

Since the regulatory review period began January 9, 1989, before the patent issued (March 27, 1990), only that portion of the regulatory review period occurring after the date the patent issued has been considered in the above determination of the length of the extension period 35 U.S.C.

¹ The original patent No. 4,912,155 was reissued on March 9, 1999 as Re. 36,128. The reissue patent appears to erroneously state that the terminal disclaimer date is September 19, 2006 (the pre-GATT, 17-year term expiration date). In the reissue application, a terminal disclaimer was filed which disclaimed the portion of the term of the patent subsequent to the original expiration date of U.S. Patent No. 4,867,907, i.e., July 27, 2007. Since July 27, 2007 (the 20-year term expiration date set by 35 U.S.C. § 154) is after the original expiration date of the above-identified patent (March 27, 2007), the terminal disclaimer does not operate to shorten the term of the above-identified patent. Both the original patent and the reissue patent claim the food additive.

§ 156(c). (From January 9, 1989 to March 27, 1990 is 442 days; this period is subtracted from the number of days occurring in the testing phase according to the FDA determination of the length of the regulatory review period.) No determination of a lack of due diligence under 35 U.S.C. § 156(c)(1) was made.

However, the 14 year exception of 35 U.S.C. § 156(c)(3) operates to limit the term of the extension in the present situation because it provides that the period remaining in the term of the patent measured from the date of approval of the approved product plus any patent term extension cannot exceed fourteen years. The period of extension calculated above, 2,242 days, would extend the patent from March 27, 2007 (35 U.S.C. § 154) to May 16, 2013 which is beyond the 14-year limit (the approval date is January 15, 1997, thus the 14 year limit is January 15, 2011). The period of extension is thus limited to January 15, 2011, by operation of 35 U.S.C. § 156(c)(3). Accordingly, the period of extension is the number of days to extend the term of the patent from its original expiration date, March 27, 2007, to and including January 15, 2011, or 1,390 days.

The limitations of 35 U.S.C. § 156(g)(6) do not operate to further reduce the period of extension determined above.

Applicant has also filed an application for patent term extension of U.S. Patent No. 4,867,907 based upon the regulatory review of the food additive AQUEOUS ARYL FLUOROPHOSPHITE SUSPENSION®. No more than one patent may be extended based upon a regulatory review period of a product. 35 U.S.C. § 156(c)(4). When applications are filed for extension of the terms of different patents based upon the same regulatory review period for a product, the certificate of extension is issued to the patent having the earliest date of issuance unless applicant elects a different patent. Applicant is hereby **REQUIRED TO ELECT** a single patent for extension. In the absence of an election by applicant within ONE MONTH of the date of this notice, and in accordance with 37 CFR 1.785(b), the application for patent term extension in the above-identified will NOT be granted.

If applicant elects the above-identified patent, upon issuance of the certificate of extension, the following information will be published in the Official Gazette:

U.S. Patent No.	:	4,912,155
Granted	:	March 27, 1990
Reissue Patent No.	:	Re. 36,128
Reissue Date	:	March 2, 1999
Original Expiration Date	:	March 27, 2007
Applicant	:	Lester P.J. Burton

Owner of Record : Albermarle Corporation
Title : Antioxidant Aromatic Fluorophosphites
Classification : 524/118
Product Trade Name : AQUEOUS ARYL FLUOROPHOSPHITE
SUSPENSION® (2,2'-ethylidenebis(4,6-Di-
tertbutylphenyl)fluorophosphonite)
Term Extended : 1,390 days
Expiration Date of Extension : January 15, 2011

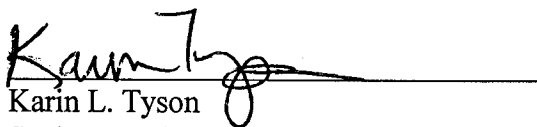
Any correspondence from applicant with respect to this matter should be addressed as follows:

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By FAX: (703) 308-6916
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Telephone inquiries related to this determination should be directed to the undersigned at (703) 306-3159.


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for Patent Policy and Projects

cc: David T. Read
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RE: AQUEOUS ARYL
FLUOROPHOSPHITE
SUSPENSION®
FDA Docket No.: 97E-0290

Enclosure: U.S. Patent No. Re. 36,128